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Amendments to the Drawings:

The attached sheets of drawings includes amendments to Figures 1 and 2. New Figure 2a has been added. These amendments have been made to address the objections made by the Examiner and do not add any new matter. These sheets replace the original sheet(s) including Figures 1-2.

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Remarks

Claims 1-14 are pending in the application, of which claims 1-14 are rejected.

Applicants respectfully traverse these rejections. By this paper, Applicants amend claims 1, 7

and 11 to address informalities, amend claim 4 to address a rejection, and cancel claims 6, 10 and

14 without prejudice in an effort to further prosecution. Accordingly, Applicants respectfully

request that the Examiner withdraw these rejections.

The drawings include pending Figures 1 and 2, of which Figures 1 and 2 are

objected to. By this paper, Applicants have amended Figures 1 and 2, and submitted new Figure

2a to address the drawing objections. Accordingly, Applicants respectfully request that the

Examiner consider amended Figures 1 and 2, and new Figure 2a.

Drawing Objections - 35 C.F.R. § 1.84

Objection of the drawings for referencing a character not mentioned in the specification

The drawings are objected under 35 C.F.R. § 1.84 (p) (5) for including reference

number (12) that is not mentioned in the specification. This has been addressed as mentioned

above by amending page 6 of the specification to reference number 12. Applicants respectfully

request that the Examiner withdraw the objection to the drawings.

Drawing Objections - 35 C.F.R. § 1.83

Objection of the drawings for not showing claimed features

The drawings are objected under 35 C.F.R. § 1.83 for not showing features of

claims 1,7 and 11. The Examiner states that the drawings do not show "the internal shape that

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allows the fluid to drain out of the valve body". The specification describes how a medium may

flow from the upstream connector 1, through the upstream contoured void 3, over the sealing face

6, through the downstream contoured void 4 and out of the valve body through the downstream

connector 2. Figure 2 is a sectional view that illustrates the internal shape of the valve that

allows fluid to flow. Figure 2 is currently amended to specifically identify the upstream void 3,

sealing face 6, downstream void 4 and downstream connector 2. Figure 2 as amended shows the

internal shape that allows the fluid to drain out of the valve body.

The drawings are objected under 35 C.F.R. § 1.83 for not showing features of

claims 5, 9 and 13. The Examiner states that the drawings do not show a thermodynamic

external body shape to maximize achievable temperature in the down stream side and

downstream connector of the valve. As stated in the spec, as currently amended: "[t]he lower

portion of the cleanable valve body, between the cylindrical heating element and discharge

connector is contoured 12, to remove metal to maximise the temperature in the downstream

contoured void and the discharge connector". This thermodynamic external body shape 12 is

shown in Figure 2.

The drawings are objected under 35 C.F.R. § 1.83 for not showing features of

claims 6, 10 and 14. The Examiner states that the drawings do not show a polymeric insulating

coating. Accordingly Applicants cancel claims 6, 10 and 14.

The applicants respectfully request the Examiner withdraw the objection to the

drawings.

Claim Rejections - 35 U.S.C. § 112

Rejection of claims 4-6, 9-10 and 13-14 as being indefinite

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Claims 4-6, 9-10 and 13-14 are rejected under 35 U.S.C. § 112, second paragraph. Claim 6 depends from claim 5, which depends from claim 4. Claim 10 depends from claim 9 and claim 14 depends from claim 13.

The valve of claim 4 is capable of providing a dry and biostatic environment on the downstream side of the valve to assist in maintaining sterile conditions (page 1, lines 4-10). In the Background Section, page 1 lines 25-26, the undesirable condition where a portion of fluid remains in a nozzle after the valve is closed is described. Under certain conditions this remaining fluid may become unsterile. Surface tension is caused by the attraction between molecules in a liquid and it explains how a liquid will adhere to a smooth surface until a force overcomes the surface tension. A person of ordinary skill designing a valve for a fluid can recognize that the interior of a valve should be smooth to facilitate flow. A person of ordinary skill could also use the principles of surface tension, along with the teachings of the present application, to appreciate how a discontinuity in a interior surface could disrupt the surface tension and encourage fluid to flow out of a nozzle. Surface tension is a function of the type of fluid in the connector. Claim 4 as currently amended requires a "small discontinuity sized to break surface tension" whereby a person would size a discontinuity to break surface tension, based on the specifics of their application. Applicant is willing to provide a declaration of a person having ordinary skill in the art to establish that this claim is not vague nor indefinite if required by the Examiner.

The valve as claimed in dependent claim 5, 9 and 13, as described on page 6 lines 7-10, is capable of heating the downstream connector using heating element 7. The heating element maintains specified temperatures at the downstream connector as well as at the sealing membrane. Heat can be transferred by a variety of modes, including conduction, where heat is transferred between contacting bodies. As described on page 6 lines 16-22, a section of the cleanable heated valve body 5, can be contoured 12 to remove metal to maximize the temperature as the medium exits the valve body, through the upstream contoured void, across the sealing membrane, through the downstream contoured void and out the downstream connector. As shown in Figure 2 the contoured section is an air gap where metal is removed between the heating element and the upstream connector. The air gap separates the heating element from the

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cool medium of the upstream connector. By removing this metal material, less heat will be conducted to the upstream connector, instead the heat will conduct and concentrate on the downstream connector and sealing membrane. The exact shape of the contoured section is not claimed by this application, however a person of ordinary skill in valve design and heat transfer and utilizing the teachings of this application, can appreciate that heat travels efficiently by conduction through a metal and by removing material forming an air gap, they can direct the conducted heat transfer.

The applicants respectfully request that the Examiner withdraws these rejections.

Claim Rejections - 35 U.S.C. § 102

Rejection of claims 1-5, 7-9, and 11-13 as being anticipated

Claims 1-5, 7-9, and 11-13 are rejected under 35 U.S.C. § 102(b) over US Patent 6,227,236 to Kusumoto et al, hereinafter Kusumoto. Claims 1, 7 and 11 are independent claims. Claims 2-5 depend from claim 1, claims 8-9 depend from claim 7 and claims 12-13 depend from claim 11.

Claims 1 and 11, as currently amended, require "an elongated heater mounted within said valve body in a location so as not to be in contact with the fluid...said heater being operative to heat the valve body". Claim 7 has a very similar requirement, except that it is in reference to a medium rather than a fluid. The Examiner relies on Kusumoto's heater 19 to satisfy this requirement. As described in Kusumoto column 5 lines 28-30, heater 19 is mounted on an outer surface of the valve chamber. This type of heater is known as heat tracing and the applicant teaches away from such heaters on page 2 lines 19-27. The internal heater of the applicant is significantly different from, and can not be anticipated by the external heater 19 taught by Kusumoto. Kusumoto teaches of a plurality of other heaters in his valve in column 5 lines 28-36, including heater 20 within the valve body. As seen in Figure 3, heater 20 is located in the flow path of the gas as it passes from the inlet 2 to the outlet 3. Although not described

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by Kusumoto, one of ordinary skill would appreciate that heater 20 requires electrical wires, that would also be in the flow path. The heaters taught by Kusumoto are not isolated away from the flow path, thus the valve taught by Kusumoto would not be suited for sterile applications. Since the applicant has designed a heater that is isolated away from the flow path, accommodating sterile applications, it is not anticipated by Kusumoto.

Claims 2-5, 8-9 and 12-13 depend from claims 1, 7 and 11 respectively and are therefore not anticipated for the reasons stated above. Moreover, these claims add further limitations which render them separately allowable.

Claims 1 & 7 require an "internal shape that allows the fluid to drain out". Kusumoto teaches of a valve to control the flow rate of a gas. Since Kusumoto teaches of a valve to control the flow of gas (Kusumoto at column 2, lines 36-40), not liquid, claims 1 and 7 are not anticipated thereby.

Claim 4, as currently amended, requires "a small discontinuity <u>sized</u> to break surface tension". Kusumoto does not discuss surface tension, nor does he teach of any features to break surface tension, therefore claim 4 is not anticipated by Kusumoto.

Claims 5, 9 and 13 require a thermodynamic external body shape to maximize achievable temperature in the downstream side and downstream connector (claim 5) and in the sealing face (claims 9 and 13). Kusumoto teaches of using a plurality of heaters to heat the valve to prevent the inner surfaces from deposits from the process gas (Kusumoto at column 5, lines 56-60). Since Kusumoto teaches of using a plurality of heaters to maximize internal temperatures of a valve and not a thermodynamic external body shape to maximize temperature in the downstream side, downstream connector and sealing face, claims 5, 9 and 13 are not anticipated by Kusumoto.

The applicants respectfully request the Examiner withdraw this rejection.

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Claim Rejections - 35 U.S.C. § 102

Rejection of claims 1-5, 7-9, and 11-13 as being anticipated

Claims 1-5, 7-9, and 11-13 are rejected under 35 U.S.C. § 102(b) over US Patent 5,941,271 to Chovan, hereinafter Chovan. Claims 1, 7 and 11 are independent claims. Claims 2-5 depend from claim 1, claims 8-9 depend from claim 7 and claims 12-13 depend from claim 11.

Claims 1 and 11, as currently amended, require "an elongated heater mounted within said valve body in a location so as not to be in contact with the fluid...said heater being operative to heat the valve body". Claim 7 has a very similar requirement, except that it is in reference to a medium rather than a fluid. The Examiner relies on Chovan's heater 90 to satisfy this requirement. As described in Chovan column 8 lines 7-11, heater 90 is an electric heater formed as a blanket and wrapped around the exterior portion of the valve body. Chovan describes a sheath 94 to fit around the heater, however the heater 90 remains external to the valve body. This type of heater is known as heat tracing and the applicant teaches away from such heaters on page 2 lines 19-27. The internal heater of the applicant is significantly different from the external heat blanket 90 taught by Chovan, therefore claims 1, 7 and 11 are not anticipated thereby.

Claims 2-5, 8-9 and 12-13 depend from claims 1, 7 and 11 respectively and are therefore not anticipated for the reasons stated above. Moreover, these claims add further limitations which render them separately allowable.

Claim 4, as currently amended, requires "a small discontinuity <u>sized</u> to break surface tension". Chovan does not discuss surface tension, nor does he teach of any features to break surface tension, therefore claim 4 is not anticipated by Chovan.

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Claims 5, 9 and 13 require a thermodynamic external body shape to maximize achievable temperature in the downstream side and downstream connector (claim 5) and in the sealing face (claims 9 and 13). Chovan teaches of using a heated blanket to heat the valve to prevent icing of the valve (Chovan at column 8, lines 14-16). Since Chovan teaches of using a heated blanket to heat the valve body and not a thermodynamic external body shape to maximize temperature at specific locations in the downstream side, downstream connector and sealing face, claims 5, 9 and 13 are not anticipated by Chovan.

The applicants respectfully request the Examiner withdraw this rejection.

Claim Rejections - 35 U.S.C. § 103

The Applicants acknowledge their obligations under 37 CFR 1.56.

Rejection of claims 6, 10 and 14 as being obvious

Claims 6, 10 and 14 are rejected under 35 U.S.C. § 103(a) over US Patent 6,227,236 to Kusumoto, in view of US Patent 6,311,710 to Facas et al., hereinafter Facas. Claims 6, 10 and 14 are also rejected under 35 U.S.C. § 103(a) over US Patent 5,941,271 to Chovan in view of Facas. By this amendment, applicants cancel claims 6, 10 and 14.

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Conclusion

In view of the foregoing, the Applicants respectfully assert that the application is in condition for allowance, where allowance is hereby respectfully requested.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted, **Gary Wayne Yewdall et al.**

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